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08/231,565	04/22/94	KAWAKAMI	Y 20264124

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18M1/0616

EXAMINER
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ART UNIT	PAPER/NUMBER
1806	16

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06/16/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/231,565

Applicant(s)
Kawakami et al

Examiner
Sheela J. Huff

Group Art Unit
1806



☒ Responsive to communication(s) filed on Mar 19, 1997

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 6-65 is/are pending in the application.

Of the above, claim(s) 6-55 is/are withdrawn from consideration.

☒ Claim(s) 62 is/are allowed.

☒ Claim(s) 56-61 and 63-65 is/are rejected.

☐ Claim(s) is/are objected to.

☐ Claims are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number)

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received:

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Response to Amendment

1.The amendment filed on 3/19/97 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 1-5 have been canceled.

Claims 6-55 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 58-65 have been added.

Claims 56-65 are currently under consideration.

2.The objection to claim 57 is withdrawn in view of applicant's amendment.

3.The art rejections under 35 USC 102 over Maresh, Gaugler or Traversari are withdrawn in view of applicant's amendment.

Response to Arguments

Claim Rejections - 35 USC § 112

~~4.~~ Claims 56-61 and 64-65 are/remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cDNA sequences of MART-1 (specifically SEQ. ID. No.1) and gp100 and allelic variations thereof, does not reasonably provide enablement for homologs thereof. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The reasons for this rejection are of record in paper no. 13, mailed 9/19/95. Applicant should note that this rejection has been modified to only apply to "homologs" and "comprising". The rejection pertaining to the "allelic variations" is withdrawn in view of the definition on page 9, lines 20-35. The rejection pertaining to the "mutiens" and "variants" thereof is withdrawn because the claims no longer recite this terminology.

Applicant argues that "homologs" is defined on page 17, line 12-30 and that the specification provides sufficient information as to the nature and characteristics of MART-1. The definition on page 17 and the specification allows for the detection of MART-1 homologs in other species, but does not define what is encompassed by "homologs". What are these "homologs"? How are the sequences of these "homologs" related to the sequence of MART-1? What changes are made in the nucleic acid sequence to result in a "homolog"? In view of the lack of a precise definition of "homolog", undue experimentation would be required by one skilled in the art to make and use the instant invention.

Applicant argues that it is impermissible to limit applicant to the examples. The Examiner is not limiting applicant to the specified examples. Applicant's are entitled to broad claims only if such claims are enabled in view of the specification and the state of the art. However, in the instant application, the specification does not provide a precise definition of "homologs" and therefore the specification is not enabled for "homologs".

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With respect to "comprising" applicant argues that "the number of peptides is delineated by three requirements" and these three are the origin of the nucleic acids sequences being MART-1, the size of the peptides and the ability of the peptide to "recognize" TIL. Applicant argues that the ability of the peptides to recognize TIL is a functional limitation. The first two requirements do not limit the number of possible peptides because MART-1 is a huge proteins and the possible number of 8 amino acid peptides is huge. The third requirement is not really a functional limitation because no specific function is recited. An example of a function is "binds", "neutralizes", "inhibits", etc.

~~5.~~ Claims 56-61 and 64-65 remain/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The reasons for this rejection are of record in paper no. 13, mailed 9/19/95. The rejection pertaining the allelic variations is withdrawn in view of the definition on page 9, lines 20-35. Please note: items a, c and e-f are withdrawn from this rejection in view of applicant's amendments.

With respect to item b, applicant argues that in view of the cancellation of claims 1-5 and in view of the arguments under 35 U.S.C. 112, first paragraph, the rejection is moot. The recited terminology in question (ie "homolog") is still present in

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the pending claims. Applicant's arguments under 35 U.S.C. 112, first paragraph, have been addressed above.

With respect to item d, applicant argues that one skilled in the art knows what "derived from" means and further cites pages 8, 35, 37 and 38). Webster's II New Riverside Dictionary (1984 p. 365) defines "derived" in four ways--one of these ways is to "produce or obtain(a compound) from another substance by chemical reaction". Applicant in this instant is producing a peptide from MART-1. It is not clear if applicant trying to claim a peptide produced after a chemical reaction or if applicant is merely claiming a portion of MART-1. At the lines specified on page 8, the Examiner sees no definition for "derived from". At the lines specified on page 35, there is no indication that the derived peptides are specifically the disclosed Seq ID's. At the lines specified on pages 37 and 38, the definition derived is not limited to those specifically recited.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 56-57 remain rejected under 35 U.S.C. 102(a) as being anticipated by Adema et al Am J. Pathol vol. 143 p. 1579 (12/93). The reasons for this rejection are of record in paper no. 13, mailed 9/19/95.

Applicant argues that Adema does not anticipate MART-1 because MART-1 and gp100 are distinct. The Examiner agrees--this rejection pertains to gp100.

Applicant argues that the limitation that the nucleic acid sequence of gp100 in the reference does not encode a protein that recognizes TIL. The nucleic acid sequence is the same as that of applicant's and therefore would have the same function.

8. Claim 56 remains rejected under 35 U.S.C. 102(b) as being anticipated by Kwon et al PNAS vol. 88 p. 9228 (1991). The reasons for this rejection are of record in paper no. 13, mailed 9/19/95.

Applicant argues that MART-1 and gp100 are distinct. The Examiner agrees--this rejection pertains to gp100.

Applicant argues that the limitation that the nucleic acid sequence of gp100 in the reference does not encode a protein that recognizes TIL. The nucleic acid sequence is the same as that of applicant's and therefore would have the same function.

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Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

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to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 56-57 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO92/21767 in view of Kwon et al PNAS vol. 88 p. 9228 (1991). The rejection pertaining the allelic variations is withdrawn in view of the definition on page 9, lines 20-35.

Applicant argues that the recited residues in WO 92/21767 does not disclose that the segment recognizes TIL. Applicant is merely claiming a nucleic acid sequence and the nucleic acid sequence, as discussed in the rejection, is obvious in view the references. The nucleic acid sequence is the same as that of applicant's and therefore would have the same function.

New Grounds of Rejection

~~12.~~ Claims 56-61 and 63-65 remain/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. In claim 56, the terminology "recognized by" renders the claim vague and indefinite. Does applicant mean "binds"? "Recognized" merely means that the TIL have the ability to bind to the peptide but they do not have to bind to the peptide (ie the peptide can or cannot interact with TIL). If applicant intends to use the "recognized" as a functional limitation then more definite terminology (such as binds) is needed.

b. In claim 58, line 1, "As" should be --An--.

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- c. In claim 61, line 2, "homology" should be --homolog--.
- d. In claim 63, line 3, the terminology "hybridizes" renders the claim vague and indefinite. Under what conditions does it "hybridizes"? Also, what does applicant mean by "stringent conditions"? "Stringent" compared to what?

Conclusion

13. Claim 62 is allowed because the prior art neither teaches nor suggests Seq ID No. 2.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (703) 305-7866. The examiner can normally be reached on Monday-Thursday from 6:30am to 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703)308-2731. The FAX phone number for this Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sheela J. Huff
June 11, 1997



Sheela J. Huff
Patent Examiner
Group 1800